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ATTORNEY DOCKET NO. 00537/184002 - 066/US/PCT/US

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Alan F. Feeney

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Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: FRANCIS X. IGNATIUS

Serial No.: 09/830,945

Filed: July 12, 2001

Title: LACTONE BEARING ABSORBABLE POLYMERS

Art Unit: 1615

Examiner: VENKAT, JYOTHSNA A

Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL LETTER AND AUTHORIZATION TO PAY FEE

Transmitted herewith is a Response to Restriction/Election Requirement mailed October 2, 2002; a Petition for Extension of Time with a Certificate of Mailing noted thereon; and Fee authorization (2 copies) together with an Acknowledgment Postcard.

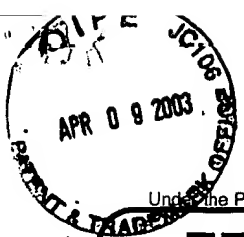
The Commissioner is hereby authorized to charge the fee due under 37 CFR 1.136(a) for the Requested Five (5) Month Extension to Deposit Account No. 50-0590. Applicant believes that no other fees are due. However, the Commissioner is hereby authorized to charge any other fees that may be deemed to be due or to credit any overpayments to Deposit Account 50-0590. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,
Biomeasure, Inc.

Date: 4-1-2003

Alan F. Feeney
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FEE TRANSMITTAL for FY 2003

Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)**1,970.00**

Complete if Known

Application Number **09/830,945**
Filing Date **July 12, 2001**
First Named Inventor **Francis X. Ignatious**
Examiner Name **Venkat, Jyothsna A.**
Art Unit **1615**
Attorney Docket No. **00537/184002 - 066/US/PCT/US**

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit
Account
Number
Deposit
Account
Name

50-0590

BIOMEASURE, INCORPORATED

The Commissioner is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	740	2001	370	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	510	2003	255	Plant filing fee	
1004	740	2004	370	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below		Fee Paid
Total Claims	<input type="text"/>	-20** =	<input type="text"/>	X	<input type="text"/>	<input type="text"/>
Independent Claims	<input type="text"/>	-3** =	<input type="text"/>	X	<input type="text"/>	<input type="text"/>
Multiple Dependent					<input type="text"/>	<input type="text"/>

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	400	2252	200	Extension for reply within second month	
1253	920	2253	460	Extension for reply within third month	
1254	1,440	2254	720	Extension for reply within fourth month	
1255	1,960	2255	980	Extension for reply within fifth month	1970.00
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,280	2453	640	Petition to revive - unintentional	
1501	1,280	2501	640	Utility issue fee (or reissue)	
1502	460	2502	230	Design issue fee	
1503	620	2503	310	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	740	2809	370	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	740	2810	370	For each additional invention to be examined (37 CFR 1.129(b))	
1801	740	2801	370	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)**1,970.00**

SUBMITTED BY

Name (Print/Type) **Alan F. Feeney** Registration No. **43,609** Telephone **508/478-0144**
Signature *Alan F. Feeney* Date **4-1-2003**

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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Attorney Docket No. 00537/184002
066/US/PCT/US

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

FRANCIS X IGNATIUS

APPLICATION NO.: **09/830,945**

FILED: **July 12, 2001**

FOR: **LACTONE BEARING ABSORBABLE
POLYMERS**

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

EXAMINER: **VENKAT, JYOTHSNA A.**

ART UNIT: **1615**

I hereby certify under 37 CFR 1.8(a) that this
correspondence is being deposited with the United
States Postal Service as first class mail with
sufficient postage on the date indicated below and
is addressed to the Assistant Commissioner of
Patents, Washington, D.C. 20231.
Date of Deposit: April 1, 2003

RESPONSE TO RESTRICTION REQUIREMENT

Responsive to the action mailed October 2, 2002 (Paper No. 7)(hereinafter "the Action"), Applicant respectfully requests consideration of the following remarks and reconsideration of the restriction delineated in the Action.

The instant application is a national stage application under 35 U.S.C. §371 of PCT International Application PCT/US99/25706. As such, unity of invention, rather than restriction, practice is applicable. See MPEP §1893.03(d). Rule 13 (Unity of Invention) of the Regulations under the PCT state that the requirement of unity is fulfilled when "there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Rule 13.2, Regulations under the PCT

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Unity of Invention practice, is also governed by MPEP §1893.03(d), which states in part:

*When making a lack of unity invention requirement, the Examiner **must** (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) **specifically describing the unique** special technical feature in each group.*

(Emphasis added) MPEP §1893.03(d).

Applicant respectfully contends that the Examiner has not met the burden of the 2nd prong of the above-stated requirement when requiring the restriction of an application. The reasons provided by the Examiner for the lack of unity are as follows:

The special technical feature of group I is a polymer where as [sic] in group II the technical feature is complex [sic] and its use in pharmaceutical compositions as well as sustained release compositions which is not present in Group I and the special technical feature of group III is treatment of a disease, which is, not present in group I or group II.

The Examiner cited no art in support of the creation of the alleged restriction groupings. The rationale provided by the Examiner is not justification for restricting the present application. The cited differences between the three designated groups, i.e., "a polymer", "a complex" and "a treatment of a disease", are not "unique special technical features" as envisioned by the Rules of Unity of Invention.

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Applicant respectfully submits that the three inventions as delineated in the Action meet the criterion of relating to a single inventive concept. As stated at MPEP §1893.03(d),

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

It is apparent, as detailed in the specification of the instant application, that claims 1-17 are directed to **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable** under normal conditions. Claims 18-22 are directed to a complex comprised of **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable** under normal conditions and a therapeutic agent. Claims 23-24 are directed to a sustained release composition composed of a complex comprised of **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable** under normal conditions and a therapeutic agent. Claims 25-26 are directed to a pharmaceutical composition having a sustained release composition composed of a complex comprised of **a polymer bearing a thermodynamically stable lactone ring considered to**

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be non-polymerizable under normal conditions and a therapeutic agent. Claims 27-30 are directed to a method of medicinal treatment by administering a pharmaceutical composition having a sustained release composition composed of a complex comprised of **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable** under normal conditions and a therapeutic agent to patient in need thereof. Applicant contends that the special technical feature to all the claims is **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable**. Applicant further maintains that the claims are analogous to Examples 1 and 15 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP. As such, the claims do exhibit "unity" and should be maintained in the present application.

The Examiner goes on to state that "the different species would require completely different searches...and [since there] is no expectation that the search would be coextensive...an undue search burden [is put upon the Examiner]." Applicant contends that the Examiner has applied conditions inconsistent with PCT Unity of Invention criteria and has instead impermissibly invoked U.S. Restriction Rules. Even if the U.S. restriction rules were

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applicable, which they are not, the Examiner deviates from the criteria for restriction as established by the MPEP regarding distinct inventions. See MPEP §803. Applicant respectfully submits that there is no requirement under the rules that the search for any claim or groups of claims be "co-extensive" with the search required for any other claim or group of claims, as the Examiner contends. The MPEP in §808.2, requires that when establishing a need for the restriction of related inventions, the Examiner must show "[the necessity] to search for one of the distinct subjects in places where no pertinent art to the other subject exists." As Applicant has demonstrated, *infra*, there is very substantial, if not complete, overlap between the searchable subject matter with respect to Group I and the searchable subject matter with respect to Groups II and III. Applicant submits that, contrary to the Examiner's opinion, no serious burden will arise from examining Group I concurrently with Groups II and III. As discussed *infra*, all of the designated groups share the technical feature of **a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable**. Thus, any search of the subject matter of either groups II or III, i.e., a pharmaceutical containing **a polymer bearing a thermodynamically stable lactone ring considered to be non-**

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polymerizable or use of said pharmaceutical to treat a medical condition, necessarily must contemplate the subject matter of Group I. Conversely, any search performed with respect to Group I, would necessarily involve significant overlap with a search performed with respect to the other Groups. Surely, the Examiner does contend that a search of a pharmaceutical containing a polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable (Group II), would not only uncover art pertinent to the patentability of the polymer bearing a thermodynamically stable lactone ring considered to be non-polymerizable, itself (Group I), but also the use of the pharmaceutical to treat or prevent a disease or condition (Group III). The Examiner's allegation that there is "no expectation that the search [sic] would be coextensive" lacks merit.

For the foregoing reasons, the Applicant submits that the restriction made in the Action was improper and respectfully requests reconsideration of that restriction and a delineation of reasoned support for distinguishing each group ultimately determined as lacking unity with each other group, as required under MPEP §1893.03(d).

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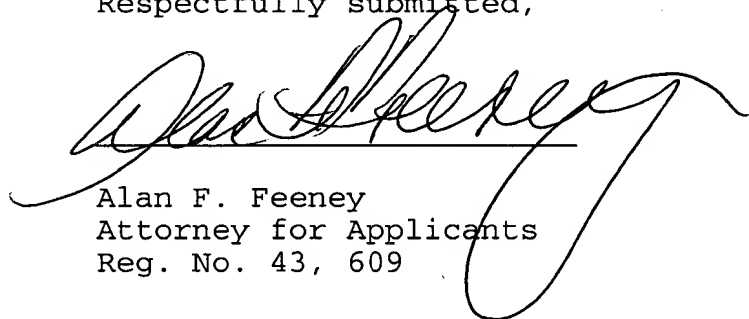
In compliance with 37 C.F.R. §1.143, Applicant elects the invention of Group I drawn to a polymer bearing a non-polymerizable lactone ring and elects a polyester (a member of the Markush list of monomer sources comprising the copolymer of claim 1) as the species of polymer. The election is made with traverse.

Prompt and favorable action is earnestly solicited.

Please apply any charges of credits to Deposit Account No. 50-0590 referencing Attorney Docket No. 066/US/PCT/US.

Respectfully submitted,

Date: 4-1-2003



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